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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR CONFIRMATION NO. APPLICATION NO. FILING DATE 10/634,211 08/05/2003 John C. Woodard DUMMER4.1CPCC1 6845 **EXAMINER** 7590 09/30/2004 KNOBBE MARTENS OLSON & BEAR LLP WHITE, DWAYNE J 2040 MAIN STREET ART UNIT PAPER NUMBER FOURTEENTH FLOOR IRVINE, CA 92614 3745

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
Office Action Summary		10/634,211	WOODARD ET AL.	
		Examiner	Art Unit	
		Dwayne J White	3745	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1)⊠	Responsive to communication(s) filed on <u>05 August 2003</u> .			
7—	·—	action is non-final.		
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims				
 4) Claim(s) 2-27 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 2-27 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 				
Application Papers				
9) The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.				
Attachment(s)				
2) Notice Notice 3) Information	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date 20030805/20040120.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:		

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the blade" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "said blades" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 2,3,5-9,11,14,15,17-21,23 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as all being unpatentable over claim 2 of U.S. Patent No. 6,638,011 in view of Izraelev (5,924,848).

Claim 2 of U.S. Patent No. 6,638,011 "anticipates" all of Patent Application No. 10/634,211 claims 2,3,5-9,11,14,15,17-21,23 and 27. Accordingly, Patent Application No. 10/634,211 claims 2,3,5-9,11,14,15,17-21,23 and 27 are not patentably distinct from U.S. Patent No. 6,638,011 claim 2. Here Patent claim 2 requires a rotary blood pump for use in a heart assist device, said pump having an impeller suspended in use within a pump housing exclusively by hydrodynamic thrust forces generated by relative movement of said impeller with respect to and within said pump housing; said pump comprising; an impeller having a plurality of blades and a hydrodynamic bearing surface; and a plurality of magnets, each magnet disposed within one of the blades, wherein an axis of magnetization of each of the magnets is inclined at any angle between and 45° to the impeller axis of rotation, while Patent Application No. 10/634,211 claims 2,3,5-9,11,14,15,17-21,23 and 27 only requires a housing, an impeller with vanes and a plurality of magnets. Thus it is apparent that the more specific U.S. Patent No. 6,638,011 claim 2 encompasses Patent Application No. 10/634, 211 claims 2,3,5-9,11,14,15,17-21,23 and 27. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Patent Application No. 10/634,211 claims 2,3,5-9,11,14,15,17-21,23 and 27 are anticipated by U.S. Patent No. 6,638,011 claim 2 and since anticipation is the epitome of obviousness, then Patent Application

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10/634,211 claims 2,3,5-9,11,14,15,17-21,23 and 27 are obvious over U.S. Patent No. 6,638,011 claim 2.

U.S. Patent No. 6,638,011 claim 2 does not recite each of the magnets being arranged within a circular zone, which is generally near the maximum radius of the impeller. Izraelev teaches a plurality of magnets 28 arranged within the impeller within a circular zone, which is near the maximum radius of the impeller. Since both the patent claim 2 and Izraelev are directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 2, with the teachings of Izraelev, by arranging the magnets within the maximum radius of the impeller for the purpose of improving interaction with the stator coils.

In regards to claims 5-7 and 17-19 of the application, patent claim 2 does not claim a particular shape for the blades. Izraelev teaches the claimed shaped blades. Since both the patent claim 2 and Izraelev are directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 2, with the teachings of Izraelev, by providing vanes shaped as claimed for the purpose of improving flow efficiency.

In regards to claims 8 and 20 of the application, patent claim 2 does not claim the vanes extending from a point near the axis of rotation of the impeller and angularly away from the axis of rotation. Izraelev teaches each of the blades extending from a point near the axis of rotation and angularly away from the axis. Since both the patent claim 2 and Izraelev are directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 2, with the

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teachings of Izraelev, by disposing the vanes as taught for the purpose of improving flow efficiency.

In regards to claims 9, 11 and 21 of the application, patent claim 2 does not claim the vane having a relatively thick end and opposing thin end or the vane increasing in width as the vane extends in a direction away from the axis of rotation. Izraelev teaches the vane having a relatively thick end and opposing thin end wherein the vane increasing in width as the vane extends in a direction away from the axis of rotation. Since both the patent claim 2 and Izraelev are directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 2, with the teachings of Izraelev, by having the vane increase in width as it extends away from the axis of rotation for the purpose of improving flow efficiency.

In regards to claim 23 of the application, patent claim 2 does not claim an electric motor including a plurality of coils mounted on, in or about the housing. Izraelev teaches mounting electric coils of the motor on the housing. Since both the patent claim 2 and Izraelev are directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 2, with the teachings of Izraelev, by mounting the electric coils of the motor on the housing for the purpose of urging the magnets within the impeller.

In regards to claim 27 of the application, patent claim 2 does not claim the blades being generally triangular in configuration, wherein the width increases with the increasing radius or the blades having a convex outer surface on the circular border of a supporting body. As stated above, Izraelev teaches the increasing width and triangular configuration. Izraelev also teaches a

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convex outer surface on the circular border of the supporting body. Since both the patent claim 2 and Izraelev are directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 2, with the teachings of Izraelev as stated above, for the purpose of improving flow efficiency.

Claims 4 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,638,011 in view of Izraelev 6,206,659. Patent claim 2 requires all of the claimed subject matter as stated above, while Patent Application No. 10/634,211 claims 4 and 16 only requires a housing, an impeller with vanes and a plurality of magnets. Thus it is apparent that the more specific U.S. Patent No. 6,206,659 claim 2 encompasses Patent Application No. 10/634, 211 claims 2,3,5-9,11,14,15,17-21,23 and 27. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Patent Application No. 10/634,211 claims 4 and 16 are anticipated by U.S. Patent No. 6,206,659 claim 2 and since anticipation is the epitome of obviousness, then Patent Application 10/634,211 claims 4 and 16 are obvious over U.S. Patent No. 6,206,659 claim 2.

U.S. Patent claim 2 does not recite the vanes forming spaced apart fluid passages or the magnets being located near the maximum radius of the impeller.

Izraelev teaches the vanes forming spaced apart fluid passages and the magnets being located near the maximum radius of the impeller. Since both the patent claim 2 and Izraelev are

directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 2, with the teachings of Izraelev as stated above for the purpose of improving efficiency and magnetic interaction with the motor.

Claims 10, 12 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,638,011 in view of Izraelev (*848).

Claim 5 of U.S. Patent No. 6,638,011 "anticipates" all of Patent Application No. 10/634,211 claims 10, 12 and 22. Accordingly, Patent Application No. 10/634,211 claims 10, 12 and 22 are not patentably distinct from U.S. Patent No. 6,638,011 claim 2. Here Patent claim 2 requires a rotary blood pump for use in a heart assist device, said pump having an impeller suspended in use within a pump housing exclusively by hydrodynamic thrust forces generated by relative movement of said impeller with respect to and within said pump housing; said pump comprising: an impeller having a plurality of blades and a hydrodynamic bearing surface; and a plurality of magnets, a single magnet disposed within one of the blades, wherein an axis of magnetization of each of the magnets is inclined at any angle between and 45° to the impeller axis of rotation, while Patent Application No. 10/634,211 only requires a housing, an impeller with vanes and a plurality of magnets. Thus it is apparent that the more specific U.S. Patent No. 6,638,011 claim 5 encompasses Patent Application No. 10/634, 211 claims 10, 12 and 22. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without

first submitting an appropriate terminal disclaimer. Note that since Patent Application No. 10/634,211 claims 10, 12, 22 are anticipated by U.S. Patent No. 6,638,011 claim 5 and since anticipation is the epitome of obviousness, then Patent Application 10/634,211 claims 10, 12 and 22 are obvious over U.S. Patent No. 6,638,011 claim 5.

Patent claim 5 does not recite each of the magnets being arranged within a circular zone, which is generally near the maximum radius of the impeller or the vanes having a relatively thick end and opposing thin end. Izraelev teaches all the claimed subject matter as stated above. Since both the patent claim 5 and Izraelev are directed towards hydrodynamic blood pumps, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of patent claim 5, with the teachings of Izraelev as stated above for the purpose of improving efficiency and magnetic interaction with the motor

Claim 24 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 22 of U.S. Patent No. 6,638,011 in view of Izraelev (*848).

Claim 22 of U.S. Patent No. 6,638,011 "anticipates" all of Patent Application No. 10/634,211 claims 24. Accordingly, Patent Application No. 10/634,211 claims 24 are not patentably distinct from U.S. Patent No. 6,638,011 claim 22. Here Patent claim 22 requires a rotary blood pump for use in a heart assist device, said pump having an impeller suspended in use within a pump housing exclusively by hydrodynamic thrust forces generated by relative movement of said impeller with respect to and within said pump housing; said pump comprising: an impeller having a plurality of blades and a hydrodynamic bearing surface on the lower surface of the impeller; and a plurality of magnets, a single magnet disposed within one of the blades,

wherein an axis of magnetization of each of the magnets is inclined at any angle between and 45° to the impeller axis of rotation, while Patent Application No. 10/634,211 only requires a housing, an impeller with vanes, a plurality of magnets and a hydrodynamic lifting surface on a bottom surface of the impeller. Thus it is apparent that the more specific U.S. Patent No. 6,638,011 claim 22 encompasses Patent Application No. 10/634, 211 claims 24. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Patent Application No. 10/634,211 claims 24 are anticipated by U.S. Patent No. 6,638,011 claim 22 and since anticipation is the epitome of obviousness, then Patent Application 10/634,211 claims 24 are obvious over U.S. Patent No. 6,638,011 claim 22.

Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of U.S. Patent No. 6,638,011. Accordingly, Patent Application No. 10/634,211 claims 25 are not patentably distinct from U.S. Patent No. 6,638,011 claim 21. Here Patent claim 21 requires a rotary blood pump for use in a heart assist device, said pump having an impeller suspended in use within a pump housing exclusively by hydrodynamic thrust forces generated by relative movement of said impeller with respect to and within said pump housing; said pump comprising: an impeller having a plurality of blades and a hydrodynamic bearing surface on the upper surface of the impeller; and a plurality of magnets, a single magnet disposed within one of the blades, wherein an axis of magnetization of each of the magnets is inclined at any angle between and 45° to the impeller axis of rotation, while Patent Application No. 10/634,211 only requires a housing, an impeller with vanes, a plurality of

magnets and a hydrodynamic lifting surface positioned on an upper surface of the impeller. Thus it is apparent that the more specific U.S. Patent No. 6,638,011 claim 21 encompasses Patent Application No. 10/634, 211 claims 25. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Patent Application No. 10/634,211 claims 25 are anticipated by U.S. Patent No. 6,638,011 claim 21 and since anticipation is the epitome of obviousness, then Patent Application 10/634,211 claims 25 are obvious over U.S. Patent No. 6,638,011 claim 21.

Claim 26 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 6,638,011. Accordingly, Patent Application No. 10/634,211 claims 26 are not patentably distinct from U.S. Patent No. 6,638,011 claim 18. Here Patent claim 18 requires a rotary blood pump for use in a heart assist device, said pump having an impeller suspended in use within a pump housing exclusively by hydrodynamic thrust forces generated by relative movement of said impeller with respect to and within said pump housing; said pump comprising: an impeller having at least three blades, hydrodynamic bearing surfaces on the upper and lower surfaces of the impeller; and a plurality of magnets wherein each magnet is disposed within one of the blades, wherein an axis of magnetization of each of the magnets is inclined at any angle between and 45° to the impeller axis of rotation, while Patent Application No. 10/634,211 only requires a housing, an impeller with at least three blades, a plurality of magnets. Thus it is apparent that the more specific U.S. Patent No. 6,638,011 claim 18 encompasses Patent Application No. 10/634, 211 claims 26. Following the

rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Patent Application No. 10/634,211 claims 26 are anticipated by U.S. Patent No. 6,638,011 claim 18 and since anticipation is the epitome of obviousness, then Patent Application 10/634,211 claims 26 are obvious over U.S. Patent No. 6,638,011 claim 18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 3, 5-15 and 17-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Izraelev (5,924,848). Izraelev discloses a blood pump 10 comprising: a housing 11; a hydrodynamically suspended impeller 20 that includes a plurality of magnets 28 arranged within the impeller within a circular zone which is near the maximum radius of the impeller. The impeller includes shark fin shaped arcuate (See Figure 3) vanes 27 that extend from a point near the axis of rotation and extends angularly away from the axis of rotation. Further the magnets are located within the vane. Each vane includes a relatively thick end and an opposed thin end.

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An axial motor formed by a plurality of stator coils 29 urges the impeller. The impeller further includes hydrodynamic lifting surfaces located on the upper and lower surfaces of the impeller.

Claims 2-4, 13-16 and 23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Izraelev (6,206,659). Izraelev discloses Izraelev discloses a blood pump 10 comprising: a housing 11; a hydrodynamically suspended impeller 20 that includes a plurality of magnets 27 arranged within the impeller within a circular zone which is near the maximum radius of the impeller. The impeller includes vanes (See Figure 2) that extend from a point near the axis of rotation and extends angularly away from the axis of rotation. Further the magnets are located within the vane. The vanes form spaced apart fluid passages. An axial motor formed by a plurality of stator coils 29 urges the impeller. The impeller further includes hydrodynamic lifting surfaces located on the upper and lower surfaces of the impeller.

Claims 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nojiri et al. (6,030,188). Nojiri et al. disclose a rotary blood pump 1 comprising: a pump housing 20 having an inlet 22, an outlet 23; an impeller 21 rotatably arranged within the housing and are urged by an electric motor and a plurality of magnets 25 disposed with the impeller. The impeller further includes hydrodynamic lifting surfaces and the impeller blades are generally triangular in shape, increasing in width as they extend in radius and have a convex outer surface.

CONCLSUION

Contact Information

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Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Dwayne J White whose telephone number is (703) 306-3464.

The examiner can normally be reached on 7:30 am to 5 pm T-F and alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Edward Look can be reached on (703) 308-1044. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dwayne White

Patent Examiner

Art Unit 3745

DJW

EDWARD K. LOOK

SUPERVISORAR, TENT EXAMINER

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9/20/04